FEB 2 8 2014

IPB Inc

K132469

510(k) SUMMARY

International Profit Builders Inc. (IPB Inc.)
"The Bite Guard"

**1. Submitted by and Contact:**

Bryan Tapocik
CEO/President of International Profit Builders Inc. (IPB Inc.)
7045 Palm Avenue
Highland, CA 92346
Tel: 909-864-7477
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Date Prepared: June 13, 2013

This Summary was amended on 12/03/2013 and any questions should be addressed to:

Bryan Tapocik
7045 Palm Avenue
Highland, CA 92346
(909)864-7477

**2. Name of Device and Name/ Address of Sponsor**

**"The Bite Guard"**

International Profit Builders Inc. (IPB Inc.)
7045 Palm Avenue
Highland, CA 92346

**a. Common or Usual Name**

Mouth guard

**b. Classification Name**

Mouth guard, Over-the-Counter

**c. Classification Product Code**
OBR

**3. Predicate Devices and Biocompatibility**

Ranir, LLC's Rest Assured Generation III Dental Protector (K091792)
Dentek's Comfort Fit Night guard (K072147) Oral B plus Outlast Nighttime Dental Guard (K113326)
Product code OBR– Our device is substantially equivalent to the above devices on the current market:

a) Same intended use
b) Same technology
c) Same device design
d) Similar physical properties as Predicate Devices
e) Similar materials
f) Same scientific concepts that form the basis of the device

IPB Inc

**4. Device Description**

"The Bite Guard" is a flexible and moldable dental protector which is a comfortable mouth guard used as a barrier between teeth for individuals who grind their teeth. Submerging the device into boiling water allows it to be molded to fit the patient's oral cavity exclusively. "The Bite Guard" is shaped like a dental arch and is constructed of a propylene-based elastomer.

**a. Indication of use**

The Bite Guard is used to prevent grinding of the teeth, jaw clenching and to reduce damage to the teeth from grinding.

**b. Comparison of Technical Characteristics of Predicate Devices – See Chart on page 26**

| Element of Comparison | Subject Device "The Bite Guard" | Predicate Device Dentek's Comfort Fit Night guard | Predicate Device Oral B Plus Outlast Nighttime Dental Guard |
|---|---|---|---|
| 510 (k) - Number | K132469 | K072147 | K113326 |
| Device Description | Flexible, moldable mouth guard used as a barrier between teeth for nighttime teeth grinding. | Flexible, moldable mouth guard used as a barrier between teeth for nighttime teeth grinding. | Flexible, moldable Mouth guard used for nighttime teeth grinding. |
| Thermal Safety | Boil and Bite Method | Boil and Bite Method | Boil and Bite Method |
| Method of Manufacturing | Injection Molded | Injection Molded | Injection Molded |
| RX or OTC | OTC | OTC | OTC |
| Reusable | Yes, Single Patient | Yes, Single Patient | Yes, Single Patient |
| Method of Disinfection | Mouthwash or Toothpaste to clean | Mouthwash or Toothpaste to clean | Mouthwash or Toothpaste to clean |
| Compatibility with Environment Other Devices | Biocompatible Materials used | Biocompatible Materials used | Biocompatible Materials used |
| Indication of Use | Prevent teeth grinding Reduces jaw clenching and damage to the teeth. | Protection Against Night grinding to reduce teeth damage. | Protection Against Night grinding to reduce teeth damage. |
| Flavored/Materials | **No Flavor Thermoplastic Resin Propylene-Elastomer** | **No Flavor Thermoplastic Resin** | **Yes Soft Propylene – Elastomer/thermoplastic** |

**c. Physical State**

"The Bite Guard" in its physical state is composed of the following ingredients:

- Propylene-based Elastomer/Thermoplastic
- Non – Flavored/ No colored additives

This presents a soft propylene-based elastomer that can be molded to the individual's teeth.

**d. Scientific Concepts**
"The Bite Guard" is based on the scientific concept of a physical barrier placed between the individual's teeth while they sleep. The barrier is intended to reduce damage to the teeth as the upper and lower teeth make contact. This is a removable appliance that is fitted to the mouth by taking an impression of the teeth when in a heated state.

**5. Technological Characteristics of the Device**

"The Bite Guard" is an occlusive night guard, fitted to the patient by the "boil and bite" method. The predicate devices are occlusive night guards as well, and also use the "boil and bite" method; therefore, The Bite Guard is technologically identical to the predicate devices. The overall shape and dimensions are identical with OTC mouth guards.

**a. Materials**

Thermoplastic Resin and Polypropylene based elastomer. When heated it fits to the individual's teeth. It is non-flavored with no color additives. In respect to indications for use and technology, the difference between the subject and Predicate Devices does not change the functional characteristics in any way.

**b. Methods of Manufacturing**

Injection mold

**6. Clinical Tests Performed/ Bench**

There were no clinical tests performed.

**Performance Data Test preformed on Predicate devices:**

"The Bite Guard" relied on biocompatibility testing as the basis for non-clinical data. The testing performed on predicate devices indicates the night guard is safe for individuals to use. "The Bite Guard" is non-flavored and has no color additives unlike its predicate Oral B plus Outlast Nighttime Dental Guard which are flavored but they have the same material, manufacturing processes, and chemical composition and sterilization methods. Attached you will find the flow chart for Biocompatibility of Toxicity test for the 501(k). Page 27

**7. Shelf Life of Device**

18 months.

A nighttime mouth guard is a product that allows the consumer to provide a barrier between their upper and lower teeth during periods in which they grind their teeth most, while asleep. The biocompatibility rationale is presented on page 26.

**10. Conclusion**

"The Bite Guard" is substantially equivalent in safety and effectiveness, design, material and chemical composition to its predicate devices except flavor. It holds up against the other mouth guards in the industry as described above.

"The Bite Guard" has identical characteristics as the other devices, a soft, formable propylene-based elastomer/ thermoplastic resin that is fitted to individuals through the boil and bite method. The Device provides a protective barrier between the consumers' upper and lower teeth to prevent grinding.

"The Bite Guard" is substantially equivalent in safety and effectiveness to Dentek's Custom Fit Night guard (K072147) and Oral B plus Outlast Nighttime Dental Guard (K113326). Ranir LLC's Rest Assured (K091792).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 28, 2014

International Profit Builders Incorporated
Mr. Bryan Tapocik
CEO/President
7045 Palm Avenue
Highland, CA 92346

Re K132469
Trade/Device Name: The Bite Guard
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: Unclassified
Product Code: OBR
Dated: June 13, 2013
Received: December 9, 2013

Dear Mr. Tapocik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

K132469

510(k) Number (if known): ~~K134951~~

Device Name: "The Bite Guard"

Indications For Use:

"The Bite Guard" IS USED TO Prevent grinding of the teeth, jaw clenching and to reduce damage to teeth from grinding.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of Center for Devices and Radiological Health (CDRH)

Mary S. Runner -S
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